

NATtrol™ BK Virus Linearity Panel

PRODUCT DESCRIPTION:

NATtrol™ BK Virus Linearity Panel (NATBK-LIN) contains purified, intact viral particles that have been chemically modified to render them non-infectious and refrigerator stable. Each panel contains five members representing a dilution series of inactivated BK Virus and one negative member to ensure consistency throughout the entire range. The panel members are supplied in a proprietary matrix.

INTENDED USE:

NATtrol™ BK Virus Linearity Panel can be used to evaluate the analytical measurement range or analytical performance of a molecular assay. This panel can also be used for operator training and monitoring assay lot to lot variation.

MATERIALS SUPPLIED:

- 6 x 0.25 mL vials at the target concentrations listed in Table 1.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on BK virus stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated BK virus and materials of human and animal origin. Safe practices suggest that the product be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that has been tested and found to be non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods.
- Heat inactivated Fetal Bovine Serum used in the manufacture of this product meets applicable USDA requirements for abattoir sourced animals, traceability, and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and postmortem at the abattoir as required by the USDA.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ BK Virus Linearity Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

LIMITATIONS:

- **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Use in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

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EXPECTED RESULTS:








- The target concentration values provided in Table 1 are tested in ZeptoMetrix in-house real-time PCR assay.
- It is the responsibility of the end user to establish their own target range and limits for the panel using their laboratory's procedures.

TABLE 1: NATBK-LIN PANEL MEMBERS

PANEL MEMBER	TARGET CONCENTRATION (copies/mL) ¹
BKV 1E8	100,000,000
BKV 1E7	10,000,000
BKV 1E6	1,000,000
BKV 1E5	100,000
BKV 1E4	10,000
Negative	Negative

¹Based on in-house real time PCR assay targeting the VP1 gene region.

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	For Research Use Only		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		